K120495
p. 1 of 1

510(k) Summary

MAY 21 2012

per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation One Boston Scientific Place Natick MA 01760
Contact Person:	Yumi Wackerfuss
Phone Number:	763-255-0785
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Prepared:	16 February 2012
Trade Name:	Impulse™ and Expo™ Angiographic Catheter
Common Name:	Diagnostic Intravascular Guide Catheter
Classification:	II
Product Code:	DQO, 21 CFR 870.1200
Predicate Device:	Impulse: K964859 (10 Feb 1997), K974559 (23 Feb 1998) Expo: K934581 (13 March 1994), K934541 (12 May 1994)

Device Description

The Impulse™ and Expo™ Angiographic Catheters are single lumen catheters offered in Selective, Pigtail and Multi-Purpose models in 5F and 6F. The devices have multiple polymer layers with a stainless steel braid embedded between the layers. The atraumatic tip does not contain braid. The proximal end consist of an insert molded polymer hub and a strain relief.

Intended Use

The Impulse™ and Expo™ Angiographic Catheters are designed to provide a pathway to be used for delivering contrast media to selected sites in the vascular system during an angiographic procedure.

Substantial Equivalence

Modified Impulse™ and Expo™ Angiographic Catheter designs, materials, manufacturing processes and intended use are substantially equivalent to the predicate Impulse™ and Expo™ Angiographic Catheters.

Summary of Non-Clinical Testing

Design verification testing, including mechanical bench testing was performed to verify that the performance of the Impulse™ and Expo™ Angiographic Catheters remain substantially equivalent to both predicate devices. Biocompatibility, sterility, and packaging testing were also performed to verify the overall safety and efficacy of the device.

Specifically the following design verification was performed:

- Shaft Stiffness
- Tip Bond Tensile Strength
- Shaft Integrity: Burst Pressure
- Hub Tensile
- Radiopacity
- Biocompatibility Testing
  - Cytotoxicity
  - Hemolysis
  - FTIR
  - Latex

Summary of Clinical Testing

Clinical Evaluation was not required for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 21 2012

Boston Scientific Corporation
c/o Ms. Yumi Wackerfuss
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K120495
Trade/Device Name: Impulse and Expo Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: April 3, 2012
Received: April 4, 2012

Dear Ms. Wackerfuss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: Impulse™ and Expo™ Angiographic Catheter

Indications for Use:

The Impulse™ and Expo™Angiographic Catheters are designed to provide a pathway to be used for delivering contrast media to selected sites in the vascular system during an angiographic procedure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120495